March 2006

The Standards Forum and Standards Actions

Visit the Technical Standards Program Web Site at http://tis.eh.doe.gov/techstds/

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Inside This Issue

Technical Standards Program Manager's Note

Hello everyone! I am pleased to present the March 2006 Standards Actions and Standards Forum. Before I provide a brief overview of the articles in this quarterly issue, and a status of the program in general, I would like to express my gratitude to Andy Lucido, a valuable member of the Technical Standards Program Office (TSPO) team. Unfortunately for us, Andy has been assigned other duties within EH and will no longer be supporting the TSP. When her talents were made obvious to other organizations, Andy became indispensable. It wasn't long before the TSP was losing a good right hand and a wonderful person. It's hard to keep someone like her under wraps!

In December 2005, the TSPO and the DOE Standards Executive, Mr. Richard Black, submitted the annual report to the Office of Management and Budget on non-government standards use and participation. As many of you know, each year we gather the information needed to compile this report. I would like to thank those of you who helped us to meet this commitment. Collecting the information actually has a secondary purpose. It allows us to update two TSP documents, TSL-1, *DOE Standards Index*, and TSL-4, *Directory of DOE and Contractor Personnel Involved in Non-Government Standards Activities*. I am happy to report that Norm Schwartz is working very hard to make this happen. I will continue to provide updates on his progress.

Jeff Feit

RevCom for TSP

Toward the end of last year, the Technical Standards Managers Committee (TSMC) and the TSPO decided to modify one aspect of RevCom. A little history: It was becoming apparent that the RevCom process needed a final step; one which would allow Technical Standards Managers (TSMs) and Subject Matter Experts (SMEs) to see first hand how their comments were being incorporated into a draft standard. This important step needed to occur prior to the standard becoming an approved document. Out of this discussion came a new feature we call "Concurrence Review" (CR). Actually, RevCom developer Doxcelerate informed us that the program was already capable of deploying this feature. Furthermore, the Directives Program's version of RevCom currently included it. To continue, it was decided that we would test the CR feature on soon-to-be-approved DOE-STD-3009, *Preparation Guide for U.S. DOE Nonreactor Nuclear Facility Safety Analysis Reports*. Our first attempt at using the CR feature included a non-redline/strikeout (RLSO) version that made it difficult for an SME or a TSM to determine how their comments were incorporated. We received immediate feedback concerning this issue and quickly opted for a change. From now on all CRs will be RLSO versions of the standards provided that the standards writer creates one in the first place. I might add that eventually Technical Standards Program Procedures will be revised to include the creation of RLSOs. In the interim, the TSPO will personally ask writers to develop RLSOs as part of the RevCom process. Hopefully this will make the feature more comprehensive. That said, I am happy to report that after a bit of a rough start, the CR for DOE-STD-3009 is posted on RevCom for TSP. Additionally, we have just posted a CR for DOE-STD-1175 *Senior Technical Safety Manager Functional Area Qualification Standard*. For those of you who use this feature, we invite your comments.

The Articles

When it comes to the applicability of international standards in the global community, Steve Cornish of the American National Standards Institute has written an interesting article entitled,

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New ISO Policy Provides International Solutions to Market Needs. The article discusses ISO's new global relevance policy. The policy calls for standards committees to consider the value of their standards from the perspective of all concerned parties. President of ASTM, James A. Thomas, wrote an article that first appeared in ASTM Standardization News entitled, *Plain Talk for a New Generation.* Like Steve Cornish's article on the new ISO Policy, Mr. Thomas' article also addresses the global standards community and its potential impact on trade.

Dennis Kubicki, EH-22 TSM, provides the first in a series of case studies to be presented in the quarterly Standards Forum newsletters. In his article entitled, *The Use of Voluntary Consensus Standards within the Department of Energy,* Dennis addresses fire protection and emergency response. I hope you will find this and future entries both interesting and useful.

Mary Haughey's article entitled, *Two Change Notices for DOE Standard 1104,* addresses the recent evolution of DOE-STD-1104, Review and Approval of Nuclear Facility Safety Basis Documents (Documented Safety Analyses and Technical Safety Requirements). In an article entitled, *New Technical Guidance on Risk Assessments,* Don Williams of the Oak Ridge National Laboratory alerts us to the Office of Management and Budget's new technical guidance on risk assessments produced by the federal government. And last but not least, our TSM Spotlight shines on Jennifer Hamilton of the Oak Ridge Office. Please take the time to read an article written about one of our highly valued TSMs.

Have a wonderful spring and I will see you in June!

New ISO Policy Provides International Solutions to Market Needs

by Steven P. Cornish

Anyone in the international business community would naturally assume that the International Organization for Standardization (ISO) develops standards that could be implemented anywhere in the world without special preference or hindrance to any affected party. Even the mission (1) of the organization calls for ISO to "develop and issue International Standards, and take action for their worldwide implementation." Yet a number of recent cases have called into question whether specific ISO standards possess the desired international applicability.

Among the examples cited were a number of ISO standards dealing with ergonomics. Global implementation was hindered because the standards were based on anthropometric parameters appropriate to the populations in Europe and North America, but not appropriate to the populations in regions such as Southeast Asia. In another case, several countries that were moving forward with plans to nationally adopt the ISO standard for cigarette lighters (ISO 9994) found it necessary to revise the maximum permitted flame height because the value included in the ISO text was not suitable for use in their region – in this instance, specific tropical conditions.

When a standard is not being used, its relevance must be called into question. As a case in point, the ISO standard on metallic flanges (ISO 7005-1) was first published in 1992, but by the year 2000 the standard was not being used anywhere in the world. In contrast, the relevant European, North American and Japanese standards enjoyed comparable worldwide market shares. Thus, Japan proposed that the ISO standard be revised to reflect market reality through the development of what is often referred to as a "co-habitation standard." Essentially, this means that the requirements in the three standards used worldwide will be incorporated into a single ISO standard and that users of the standard will be able to make selections according to the region and markets in which they wish to operate.

Another concern, and one that has been cited frequently, is that of perceived European dominance in ISO and the view that ISO standards are written to suit the European Union regulatory regime. Any undue influence from a particular region can lead to the development of an international standard that may not be suitable for implementation where the regulatory and legal regimes or embedded technology and practices may be different.

Six Guiding Principles of Global Relevance

The formation of the World Trade Organization, and the subsequent adoption of the WTO Technical Barriers to Trade Agreement, have placed new obligations on standards developing organizations. In essence, the international standards that these organizations develop, adopt and publish must support global trade and must be globally relevant. The development and adoption of an

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international standard that fails to meet WTO requirements is open to being challenged as creating a barrier to free trade (see sidebar below).

A globally relevant standard should:

- Effectively respond to regulatory and market needs (in the global marketplace);
- Respond to scientific and technical developments in various countries;
- Not distort the market;
- Have no adverse effects on fair competition;
- Not stifle innovation and technological development;
- Not give preference to characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions;
- Be performance-based as opposed to design-prescriptive.

[Source: Document G/TBT/1/Rev.8, formerly referred to as Annex IV to the Second Triennial Review of the Technical Barriers to Trade Agreement.]

Upon consideration of the cases noted above, as well as the provisions spelled out by the WTO, ISO's management bodies were compelled to provide fuller advice on global relevance to the ISO technical committees and subcommittees. Over a period of several months, and with intensive international cooperation and collaboration, ISO developed and approved a complete global relevance policy. The first step was the organization's definition of global relevance as "the required characteristic of an International Standard that it can be used/implemented as broadly as possible by affected industries and other stakeholders in markets around the world."

The new ISO Global Relevance Policy and Principles Document hinges on the six principles identified below. Further practical details are provided in an accompanying ISO Global Relevance Implementation Guidance Document.

Principle 1

The status and meaning of an international standard shall be respected.

Any ISO standard shall, to the extent possible, represent a unique international solution. If a single solution is not currently possible due to legitimate market and essential differences – factors such as legislation, climate, environment, economies, social conditions, trade patterns, etc. – then the resulting standards may present options to accommodate these differences.

Principle 2

The commitment to participate in the development and the feasibility of preparing international standards shall be demonstrated at the outset of a standards development project.

When various solutions exist in order to meet unique aspects of the local markets in different regions and countries, the evolution of a single global market can be hindered. However, imposing a single solution that accommodates the needs of one market, but not others, may force that market – and its related industries – to look elsewhere for a standard that better accommodate its needs. Educated decisions must be made.

ISO committees shall now ascertain at the outset of a project which of three possible options is feasible for the work at hand:

1. Develop an ISO standard that presents one unique international solution in all of its provisions;
2. Develop an ISO standard that presents options in specific provisions to accommodate existing and legitimate market differences where justified; or
3. Undertake no development work because the preparation of a globally relevant ISO standard is not feasible at the present time and under the present conditions.

Principle 3

Preference shall be given to preparing performance rather than prescriptive standards.

The use of the performance-based approach is widely recognized as supporting the development of globally relevant standards. Annex 3 of the WTO Technical Barriers to Trade Agreement calls for standardizing bodies to, wherever appropriate, "specify standards based on product requirements in terms of performance rather than design or descriptive characteristics." The procedures governing the work of ISO and the International Electrotechnical Commission (IEC), also stress the need for maximum freedom in technical development, placing emphasis on requirements that are expressed in terms of performance rather than design-based or prescriptive characteristics. (2) In practice, there may be cases where the development of a set of requirements that are completely design-based is not only appropriate, but also helps to ensure global relevance. There may be other cases where a standard that is largely performance-based may appropriately include design requirements for certain provisions. Which approach is most appropriate depends on the technical matter in question and which characteristics are suitable for worldwide, or "universal,"

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acceptance.

Principle 4

Given existing and legitimate market differences, an ISO standard may pass through an evolutionary process, with the ultimate objective being to publish, at a later point, an international standard that presents one unique international solution in all of its provisions.

An ISO technical committee or subcommittee will also consider how best to address the current and potentially changeable differences in markets that impact the ISO deliverables they produce. Such changeable factors range from legislative requirements to social conditions, including trade patterns and market needs, scientific theories, design philosophies, and more.

In some cases, an ISO committee may choose to develop performance requirements that can then be supported by more detailed regional or national standards. Though there are few applications of such approaches, one recently published example is ISO 19938: 2003, Performance and Assessment Requirements for Design Standards on Structural Concrete, which lists regional consensus standards that are "deemed to satisfy" the requirements of the international standard.

When market differences call for options to specific provisions, the alternatives may be presented in parallel clauses in the main body text, in normative annexes or in sub-parts of the standard. Whichever form the options take, the committee will ensure that all options are treated equally. ISO Technical Committee 153 Subcommittee 1 has chosen to develop ISO 7121, Metal Ball Valves for General Purpose Industrial Applications, using parallel clauses in the main body text. ISO/TC 23/SC 3 is developing ISO 4254-1, Agricultural Equipment – Safety – Part 1: General Requirements, using normative annexes. In all cases, the intent is to keep to a minimum the number of optional requirements within the standard.

Principle 5

Essential differences consistent with Annex 3 to the WTO Agreement on Technical Barriers to Trade can be included in international standards.

Embedded technological infrastructures and climatic, geographical or anthropological differences are factors that will rarely change over time. Because certain committees may need to consider how these essential differences impact the standards they are developing, specific rules have been detailed in the ISO implementation guidance document.

Principle 6

Committees can only ensure the global relevance of the international standards they produce if they are aware of all the factors that may affect a particular standard's global relevance.

The participation of all relevant ISO member bodies is seen as a major factor in supporting global relevance. Developing countries frequently have difficulty acquiring the capability, expertise and resources to participate directly, but experts from more developed markets may also be precluded from participation. Whatever the reason, it should be expected that the participating committee members – whether leaders, delegates or contributing experts – should be aware of the specific needs of non-participating, but materially affected parties. Because manufacturers and service providers are very aware of the needs in all markets where they conduct their business, the representatives of these organizations are seen as having a particular responsibility, and perhaps even an ethical duty, to bring this market knowledge into the standards development process.

Making a Difference

Recently, a larger number of European voting members than non-Europeans comprised the membership of the ISO committee on boilers and pressure vessels (ISO/TC 11) and the committee on welding (ISO/TC 44). This imbalance during the standard development process was leading to content that reflected the European regulatory regime to the exclusion of approaches that would be responsive to markets in other nations and regions. At the American National standards Institute's request, the ISO Technical Management Board decided to apply the new ISO global relevance principles, effectively halting the progress of work projects in both committees until work plans could be developed that would realize globally relevant documents.

The real value of ISO's new global relevance policy is that it calls for each committee to consider more carefully the value of the standards that it provides and to consider that value from the perspective of all concerned parties, not just from the view of the committee's voting members. The market profiles and needs analysis results must then be incorporated into the business plans that have been developed and maintained for each ISO committee. These Plans serve as important reference points as the Committees work to develop requirements that acknowledge, address and evolve with ever-changing market and essential differences.

"One standard, one test, accepted worldwide" is a laudable goal set by ISO, but it is only achievable if another element exists as a precursor: one global market. Evolving dynamics mean that a single global market does not yet exist in all cases. However, the ISO

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global relevance policy presents countless new opportunities to engage interested and affected parties in the development, promulgation and implementation of international standards that can accommodate market, societal and essential differences while moving toward a single international solution.

References

1. Article 2.2.2, ISO Statutes and Rules of Procedure
2. ISO/IEC Directives, Part 2, Clause 4.2 (Performance approach)

About the Author

Steven P. Cornish is employed by the American National Standards Institute (ANSI) as a director of international policy, where he focuses on the policy and governance issues of ISO. Cornish currently serves as the ANSI representative on the ISO Technical Management Board and a number of its subgroups. In his 15 years at ANSI, he has worked with U.S. interests on national, regional and international standardization in a variety of sectors including image technology, medical devices, safety and health, and the environment.

Plain Talk for a New Generation

The Changing Dynamic of the Global Standards Community and Its Potential Impact on Trade

This article is adapted from a speech given by ASTM President James A. Thomas at the Global Policy Summit on the Role of Performance-Based Building Regulations in Addressing Societal Expectations, International Policy, and Local Needs, held at the National Academy of Sciences Building, Washington, D.C., on Nov. 5, 2003.

The phrase “global village” was coined in 1967 by the brilliant Canadian-born intellectual, Marshall Herbert McLuhan. Commenting on the effects of television, he said, “The new electronic interdependence recreates the world in the image of a global village.”

We speak of a global market. We call our construction regulatory community a global community and our standards community a global community. And yet, I am reminded that what McLuhan said was not that our electronic interdependence would recreate the world in a global village, but that it would recreate the world in the image of a global village.

ASTM International and the building community share a long and auspicious history. It started in 1898, with the formation of the first ASTM technical committee — Committee A01 on Steel, Stainless Steel, and Related Alloys. A01 immediately began to draft specifications for steel used in buildings and bridges and, by 1901, it had developed one of ASTM’s first standards, a specification for structural steel for bridges. ASTM International was then known as the American Section of the International Association for Testing Materials. Today, Committee A01 has approximately 600 members, and jurisdiction over 485 standards. In 1902, another committee was formed — C01 on Cement — and from that day to this, the building community has been an indispensable part of the ASTM International process.

The same is true of the regulatory community. You are the largest single user of ASTM standards, and an active partner in developing them. More than 1,550 ASTM construction specifications, practices, and test methods now appear in international building codes and regulations around the world. The connection between our communities is crucial because, like threads in a cloth, they are interwoven and interdependent. If we are indeed to build a global village and a coherent global market, we will have to do it together. I am, therefore, gratified that standardization has a place in this discussion.

The global standards community is a mirror that reflects conditions in the world market. This was dramatically evidenced in what was perhaps the first notable shift in the standards community in the last century — the formation of consortia, where traditional processes were traded for those that were designed for speed. This shift was most noticeable in the information technology and

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automotive industries, but in the United States and in other parts of the world, other sectors were beginning to demand global standardization that was direct, efficient, and flexible — standardization that was evolving in tandem with the world trading system.

As the role of tariffs decreased in the global marketplace, the role of standards increased. In the global marketplace, standards were now expected to act as passports to multiple markets, the means by which producers were able to satisfy ranges of regulatory requirements. And they were expected to act as technical competitive devices as well, able to imbue products with exciting new qualities and advances in technology.

Producers, now newly invested in the development of these very effective market tools, began to pay more attention to the processes by which they were developed. Products with short shelf lives required a standards process that was streamlined and built for speed.

Others needed unencumbered, direct participation in a global process in which they could develop high quality, cutting edge technology and market relevant standards. Still others preferred to achieve market success using a process whereby national delegations developed standards that were aligned with industrial policies. Some required a process that included a wide range of interests and geographical diversity, while others chose national or regional interests exclusively.

In short, producers had discovered the value and the logic of performance-based processes for developing standards, and there was no going back. The global market and the General Agreement on Tariffs and Trade created the environment for the rise of a global standards system that was flexible and responsive to sector-specific requirements. But while the changes in the system have proved to be extremely effective, they have created unrest in those who are still invested in the more traditional — and prescriptive — methods of standardization. There is disagreement among the ranks.

The World Trade Organization's Technical Barriers to Trade Agreement, the follow-up to the General Agreement on Tariffs and Trade, is a focal point for much of the dispute. While the goal of the Technical Barriers to Trade Agreement is to liberalize trade through the fair practice of standardization, it also offers guidance and principles for governing the development of standards. It advocates the use of international standards and performance-based standards, two topics that relate directly to this summit meeting. Wisely, the agreement does not prescribe the methodology by which standards are to be developed. It has not explicitly chosen one process over another. It is this point that is the subject of debate; questions surround its intent.

The debate inspired the U.S.- domiciled standards community to examine the question of performance-based standardization processes. It first noted the fundamental difference in philosophy that exists between the United States and most of the rest of the world. The American regulatory framework, for example, reflects the realities of market forces and the involvement of societal interests. Likewise, regulators are more directly and equitably involved in the standardization process than in other parts of the world. Government use of voluntary standards and the practice of government-private collaboration in the development of standards are codified in the National Technology Transfer and Advancement Act of 1995.

Three years ago, a group of regulators, industries, and standards organizations, under the aegis of the American National Standards Institute, formulated a National Standards Strategy for the United States. It espoused a liberalized world standards system that reflected a liberalized world trading system. It embraced the principles of the World Trade Organization's Technical Barriers to Trade Agreement. The strategy states that global standardization is appropriate wherever it best serves the interests of its stakeholders. Like the Technical Barriers to Trade Agreement, it does not prescribe the methodology by which global standards are to be developed.

The global standards community is clearly in a time of transition and evolution. What has been the effect of this evolution on the global market? It pragmatically selects the process and venue that are most appropriate and uses the standards that are most successful. This process is, at times, at odds with regulatory policies that prescribe unrealistic or unworkable standards solutions. That is why this summit is so important and this discussion so vital.

In the organization I represent, that selection process has resulted in a membership that now includes citizens from 104 countries. The standards that are produced by the ASTM process have been selected for use in more regulations in more countries than we have been able to count. We believe that it is our system of direct participation, unqualified openness, and dedication to freedom of choice that attracts our global participants. What is perhaps most important, however, is that where these standards are used, the levels of health and safety are raised. We know that the quality of life is enhanced, and that the environment is more sustainable. All evidence seems to point to the conclusion that the selection process has raised the bar for excellence in all of the processes. And that is a clear benefit for everyone. It is global progress.

We know that the term "global," no matter how hopefully it is used, is not a synonym for cohesion or congruity. Upon what, then, can differing systems agree? In the standards experience, the agreement has been on the principles that underpin standardization: openness, transparency, impartiality, and consensus, the same principles that are outlined in the Technical Barriers to Trade Agreement. They are greater than our institutions, and greater than our differences. They are beyond dispute and above the debate. Many of today's global industrial leaders are indifferent to that debate in any case; and the next generation will most likely find it irrelevant. One day, the debate will be history. And the principles will still be there to guide us, to offer us the cohesion,

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congruity, and the freedom of choice that we hold before us. And we will, at last, live up to our image.

James A. Thomas
President, ASTM

The Use of Voluntary Consensus Standards within the Department of Energy

Case Study: Fire Protection and Emergency Response

By: Dennis Kubicki, Office of Facility Operations Support, EH-24, (P.E)

Editor's Note: This is the first of a series of articles in the Standards Forum that addresses the use of Voluntary Consensus Standards (VCS) by the Department of Energy (DOE) as required by Office of Management and Budget (OMB) Circular A-119.

DOE has historically used the codes and standards promulgated by the National Fire Protection Association (NFPA) in the development and implementation of fire safety and emergency response programs at its sites. The criteria contained within them address a host of conditions that span a wide spectrum. They include all facets of the design and construction of facilities, the identification and control of fire and related hazards, the testing and maintenance of fire protection equipment, training, the administration of fire protection programs and emergency services organizations, among many other issues.

DOE and its predecessor agencies (AEC, ERDA) have utilized these codes and standards in lieu of department-specific directives for a number of reasons. NFPA is universally recognized for the diverse expertise of the members of its technical committees. (DOE and its contractor employees are widely represented within these committees.) The scope of fire safety and emergency response issues with the Department is vast. Attempting to address them solely with internal directives would be cost prohibitive.

Dennis Kubicki

Because the management and administration of the Department's sites and facilities are by contractors, DOE mandates the adoption of NFPA codes and standards by the contractors through the DOE directives system. These directives include Contractor Requirements Documents (CRD), which correspond to the requirements of DOE Orders. The CRDs, in turn, are incorporated directly into specific contracts, as applicable.

All NFPA codes and standards feature language allowing for the adoption of alternate fire protection and emergency response configurations based on achieving "equivalent" levels of safety. This "Equivalency Principle" allows for the flexible and cost-effective implementation of requirements. Over the last seven years, DOE has saved literally hundreds of thousands of dollars within the realm of inspection and testing of fire protection systems through the adaptation of this principle, as delineated in NFPA Standards 25[1] and 72[2], to site circumstances. Comparable savings have been achieved in the design, construction, modification and operation of facilities, among other areas.

While DOE maintains a very limited set of Department-specific fire safety directives to address unique circumstances, it relies overwhelmingly on NFPA codes and standards for defining comprehensive fire protection programs that achieve acceptable levels of safety in a cost-effective manner.

For any questions in this regard, I can be reached by phone at (301) 903-4794 or e-mail: Dennis.Kubicki@eh.doe.gov.

[1]Inspection, Testing and Maintenance of Water-Based Fire Protection Systems
[2]National Fire

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Two Change Notices for DOE Standard 1104

By Mary Haughey, Office of Nuclear and Facility Safety Policy, EH-22

My Irish aunt refers to the birth of two babies within an eighteen month span as "Irish Twins." The end of 2005 produced a set of Irish Twins for DOE Standard (STD) 1104, Review and Approval of Nuclear Facility Safety Basis Documents (Documented Safety Analyses and Technical Safety Requirements), in the form of two change notices issued in rapid succession. Change Notice 2 was issued in November 2005 and Change Notice 3 was issued in December 2005. These change notices were each very narrowly focused on a single topic.

On January 31, 2005, the Defense Nuclear Facilities Safety Board (DNFSB) sent a letter to DOE expressing concern about the available guidance on the use of "conditions of approval" for nuclear safety bases. Section 830.202 of the Nuclear Safety Management Rule (10 CFR Part 830) states that contractors must incorporate in the safety basis any changes, conditions, or hazard controls directed by DOE. The regulation also states that the safety evaluation report issued by DOE must document the basis for approval of the safety basis for the facility including any conditions of approval. We met with the DNFSB and they shared their findings and experience with the application of conditions of approval to DOE safety bases. We agreed that additional guidance would be helpful to ensure more consistent and appropriate use of the conditions of approval provision in the approval of nuclear safety bases. After drafting new language on conditions of approval, draft Change Notice 2 to DOE Standard1104 was posted for review on RevCom for TSP, but commenters were instructed to restrict their comments to only the topic of conditions of approval. We received comments from DOE and contractors through the RevCom for TSP process and from DNFSB staff by letter. In both cases comments addressed conditions of approval, as well as other issues, and in both cases we were able to consider only the comments related to conditions of approval for Change Notice 2.

One set of comments to Change Notice 2 alerted us to a second commitment to the DNFSB that affected DOE STD 1104, namely the commitment to add references to software safety to the standard. Consequently, once Change Notice 2 was issued we immediately reviewed the software safety commitment. We determined that two small changes to section 1.2 were needed to meet this commitment. Furthermore, we determined that these changes were not substantial and did not need to be reviewed through the RevCom process. Hence, Change Notice 3 was quickly processed to meet the commitment to the DNFSB and issued the following month. As a result, Change Notice 2 found itself moved to the archive pages of the TSP web site only one month after it was issued.

We had some technical glitches with Change Notice 3 in the PDF conversion. The first conversion that was posted on the web site missed the actual changes to section 1.2. It is easy to check if you have this version. If a search on the word "software" does not produce two hits in Section 1.2, then please revisit the web site for the updated version.

The second glitch involved the disappearance of one heading and the renumbering of another. The section title for 1.3 disappeared and the section title for 1.4 got renumbered to 1.3. In this version, only the header is missing so the text for 1.3 can be read as a continuation of section 1.2. If you do not have a section numbered 1.4 in your copy of the standard, please visit the web site to get an updated version of the standard with the header restored.

Last, in the process of producing these change notices we realized that it is indeed time to initiate a full revision to the standard. This year I will be reworking the standard and am looking for comments, suggestions, and subject matter experts who are willing to review and comment on multiple drafts of the standard in advance of posting a draft revision on the RevCom for TSP. Please send me your email address if you are willing and able to assist in the update. I can be reached by phone at (301) 903-2867 or e-mail: Mary.Haughey@eh.doe.gov.

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New Technical Guidance on Risk Assessments

By Don Williams, Group Leader, Reactor & Facility Safety
Oak Ridge National Laboratory, Oak Ridge, TN

Standards for Risk Assessments

The White House Office of Management and Budget (OMB) is proposing new technical guidance on risk assessments produced by the federal government. A draft bulletin on the subject was released for public comment on January 9, 2006. In addition, the National Academy of Sciences has been requested to conduct a peer review of the draft bulletin.

Risk assessment is a widely recognized and accepted analytic tool for estimating the likelihood and severity of risks to human health, safety, and the environment. It acts as a tool for professionals in making informed decisions on how to manage those risks. Transparent and accurate risk assessments are necessary for agencies and other decision makers to make wise risk management decisions during the formation of agency rules and policy decisions. For the purposes of this Bulletin, the term "risk assessment" refers to a document that assembles and synthesizes scientific information to determine whether a potential hazard exists. Also, risk assessments help to evaluate the extent of possible risk to human health, safety or the environment.

"This Bulletin provides clear, minimum standards for the scientific quality of federal agency risk assessments. We look forward to comments from the National Academy of Sciences on how the Bulletin can be improved," said Dr. John D. Graham, Administrator of OMB's Office of Information and Regulatory Affairs.

The OMB bulletin, prepared in consultation with the Office of Scientific and Technical Policy (OSTP)* defines general risk assessment and reporting standards for agency risk assessments and defines special standards for influential agency risk assessments. Standards for risk assessments used in regulatory analysis are also defined. OMB anticipates the new guidance will facilitate faster peer reviews of risk assessments and decrease the need for document revisions.

*OSTP came into being through congressional scientific and technical information (STI) initiative under the "National Science and Technology Policy, Organization, and Priorities Act" of 1976. Being a science advisor to the President, the OSTP Director acts as a focal point in the Executive Office on all scientific and technical issues.

The proposed bulletin includes guidance related to:

- Objectivity,
- Reproducibility,
- Transparency and presentation,
- Risk characterization, and
- Uncertainty characterization in risk assessments.

OMB will modify the bulletin, as appropriate, based on the National Academy of Sciences review, comments received from the public during the public comment period, and comments from federal agencies. The bulletin is scheduled for completion in late 2006.

A copy of the draft bulletin is available on OMB's website at:
http://www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf.

Interested parties should submit comments to OMB's Office of Information and Regulatory Affairs on or before June 15, 2006. Comments may be submitted electronically to OMB_RAbulletin@omb.eop.gov or by facsimile to (202) 395-7245. For further information, contact Dr. Nancy Beck, OMB, 725 17th Street, N.W., New Executive Office Building, Room 10201, Washington, D.C. 20503, (202) 395-3093.

For any questions, I can be reached by phone at 865-574-8710 or by e-mail: williamsdljr@ornl.gov.

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Technical Standards Manager Spotlight

Jennifer Hamilton, Technical Standards Manager
Oak Ridge Office, Oak Ridge, Tennessee

Just let me take this opportunity to thank the TSP Newsletters General Editor Satish Khanna for asking me to be in the Technical Standards Manager Spotlight. I am always eager to share with the world what we do here in Oak Ridge. I also get very excited to talk about the beauty of my native Tennessee, which I dearly love.

Jenni Hamilton

I serve in several functions at Oak Ridge, as many of you do at your facilities. My first responsibility is as the Directives Point of Contact for all of the Oak Ridge multi-program facilities under Science, Environmental Management, and Nuclear Energy. My second responsibility is as the Technical Standards Manager for these facilities. Until recently, I also coordinated all directives and technical standards actions for the Oak Ridge Y-12 National Security Complex. It seems odd now not to have them as a part of our review family, but our Service Agreement ended December 2, 2005 and they are now operating on their own.

Many of you know that I live in Lenoir City, Tennessee, which is the Lake Capital of the South. We have three lakes from the Tennessee River in my small town. We also have three of the Tennessee Valley Authority's dams, Fort Loudoun, Tellico, and Melton Hill. In fact, the Fort Loudon Dam is built on three islands that my mom's grandparents owned; and my dad worked on the first earth-moving construction team for the dam before going into World War II. Tennessee is gorgeous and now all of you know why Rick Serbu, past TSP Program Manager, chose to move here when he retired.

Oak Ridge has provided many people in this area with wonderful careers. However, many people also travel very far to come here because they can enjoy the atmosphere of small town life yet work in companies involved in scientific developments, continually on the verge of new discoveries.

The Manhattan Project was the beginning of Oak Ridge under the Atomic Energy Commission. When I started working for the Department, it was still the Energy Research and Development Administration (ERDA), up until then my life had been rather diversified. I started college in music as a Grace Moore Vocal Scholarship finalist, then changed to fashion merchandising. However, neither were hardly fields of study that the government was looking for, but they helped me get my foot in the door. Soon I learned I needed more, and went back to school at night to get another degree in Business Administration. This finally started my career moving upward instead of sideways. There again I am not your typical Science type, but my background has given me the opportunity to understand things in different ways from many people. Sometimes it is very helpful to be a creative-type when things need to be changed or given a different perspective.

The group I work in; the Directives Management Group, was formed in 1992 as a result of a Directives Task Force study. That task force took a two-person operation to, at the maximum, 19 people, who evaluated the necessity of requirements within the directives to see if requirements could be incorporated by other methods. Those methods started out as Standards/Requirements Identification Documents (S/RIDs), for which we developed massive data bases. Contractual requirements were also changing with the incorporation of what is called the "laws clause" of the Department of Energy Acquisition Regulations, so the work load was tremendous.

Our group worked through all those changes and has seen many more come about with the move from S/RIDs, to Necessary and Sufficient, and now to Work Smart Standards. This was a real eye-opening experience for me – to think that a small group of two could grow into something so large and have so much impact all over the Oak Ridge Office (ORO) Reservation. We still monitor each prime contract operating within the ORO Reservation and prepare all contractual changes relating to directives and technical standards.

I believe the Technical Standards incorporated into all these different stages of regulations have allowed contractors to be more flexible and more efficient. Previously, the Technical Standards were incorporated into many of the directives. The Department then chose to change from strict adherence to certain policies to giving choices to our contractors on ways that they could accomplish their tasks. By allowing contractors the opportunity to do what they believe is necessary to complete their job, the DOE has been promoting quality culture in the complex.

The Directives Management Group (DMG)at ORO, though quite small now, is a hard-working, diligent team with very broad

Continued on next page

regulation knowledge whose functions are an integral part of the overall office mission. The DMG has worked in the development of each of the ORO Functions, Responsibilities, and Authorities Manuals, (FRAMs). These documents have evolved from focusing on only one building at the Y-12 Complex to incorporating all programs into a complex-wide safety manual. The DMG has also worked with ORO Management to develop the ORO Management System Description, (MSD) describing all aspects of work in each organization at ORO.

The ORO Complex is very diverse with a broad range of programs, but the DMG is involved in all areas. These include integrated safety management, delegations of authority, implementation planning for contractors, base lining contractual documents, tracking requirements for all the M&O/M&I contractors, S/RIDs and Work Smart Standards (WSS). Additional tasks cover reviewing all draft directives and technical standards, tracking and preparing data bases for all of that information, and maintaining the largest historical directives library within the Department. We are currently working on developing the Science Management System that will be an action-tracking data base to be used throughout all of the DOE Science organizations. We have also been a part of each beta REVCOM test, assisting in quality development of the systems, both for directives and technical standards, by providing input into making each more user-friendly.

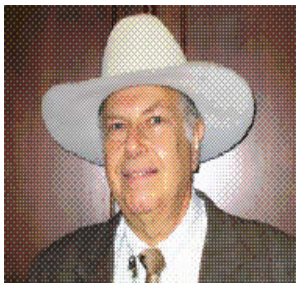
Since I came to the Directives Management Group in 1987 and was selected the Technical Standards Manager in 1999, life here has never been boring. The Technical Standard Program at ORO is a very good program that has grown substantially the last few years, and it is very well respected. We have a number of people working on core committees either writing or overseeing the development of new technical standards, which in itself, is a lot to be said for the technical expertise we have here in Oak Ridge. As you can tell, I love being a part of what is Oak Ridge, the history, the present and the future.

I take great pride in my work and enjoy the interface I have with all organizations at ORO and our contractors, but when I'm not working, I dearly enjoy music, sports, and landscaping, and just the beauty of the area where I live. Most of the back roads I have traveled with my three great kids, exploring sites that only folks here get to see. Oak Ridge has provided an excellent career for me, in the Tennessee that I love; where I choose to live on the back of the East Tennessee farm where I was raised. If you haven't been to Tennessee, come and visit. You'll want to stay!

For any questions, I can be reached by phone at 865-576-0681or by e-mail: hamiltonjg@oro.doe.gov.

Topical Committee Developments

Nothing to report in this Issue.



M. Norman Schwartz

Meeting Notice: Metrology & Accreditaion Committee Meeting

The DOE Joint Metrology and Accreditation Topical Committee plans to hold its annual meeting at the AmeriTel Inn, 645 Lindsay Boulevard, Idaho Falls, Idaho, from April 11-13, 2006.

Continued on next page

Welcome Aboard the TSMC!

(By M. Norman. Schwartz, Office of Nuclear & Facility Safety Policy)

The **T**echnical **S**tandards **M**anagers (TSMs) are the backbone of the DOE Technical Standards Program! These knowledgeable individuals serve as their organization's standards point of contact and contribute to the coordination of Department-wide TSP activities. A great deal of their work time is spent in assuring that standards activities take place in a manner that will promote safe, economical, and efficient operations locally and across the DOE complex.

With nearly 90 active and mobile people involved in TSM activities, it can be a daunting task just to keep up with the retirements and reassignments affecting the TSM roster. This "Welcome Aboard" feature is designed to introduce you to the new TSMs and help you keep abreast of the rapidly changing make-up of the Technical Standards Managers' Committee (TSMC).

The following is the recent change in the membership list:

Lloyd A. Hill (Replaces Michael C. Johns as TSM)
Technical Standards Manager
Bonneville Power Administration (DOE)
P. O. Box 3621-T-OPP3
Portland, OR 97208-3621
Phone: 360-691-6286
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STANDARDS ACTIONS

1.0 DOE STANDARDS ACTIONS

The complete list of all DOE Technical Standards projects and their status is available on the Technical Standards Program (TSP) web page at http://www.eh.doe.gov/techstds/. To access these standards, go to our web page, click on "DOE Technical Standards," then choose Projects, Approved Standards, Recently Approved Standards, or Drafts for Review, as appropriate, on the left frame of the page.

1.1 New Projects and DOE Technical Standards in Revision

The following entries were received in February 2006:

- *User's Guide for Mayak Worker Historic Radiation Dose Database (Doses-2005):* SAFT-0106.

  Volume I - Overview of Methods Used in Preparation of Doses-2005 database

  Volume II - Dose Reconstruction Methods Used in Preparing External Doses

  Volume III - Dose Reconstruction Methods Used in Preparing Internal Doses

Contact Joel L. Rabovsky; Phone: 301-903-2135, Fax: 301-903-2135, e-mail: joel.rabovsky@eh.doe.gov.

1.2 DOE Technical Standards Posted in RevCom for TSP

Your Technical Standards Manager (TSM) will initiate requests for specific reviewers to comment on these drafts. The list of TSMs can be found at: http://www.eh.doe/techstds/contact/stdmgrs.html. The full test of these documents are available for comment at RevCom for TSP (http://standards.doe.gov/login.jsp) accessed from the TSP website.

No entries were received in February 2006.

1.3 DOE Technical Standards in Reaffirmation

No entries were received in February 2006.

1.4 DOE Technical Standards Change Notices

No entries were received in February 2006.

1.5 DOE Technical Standards Published

No entries were received in February 2006.

2.0 NON-GOVERNMENT STANDARDS ACTIONS

2.1 American National Standards Institute

American National Standards Institute (ANSI) publishes coordination activities of non-Government standards (NGS) weekly in ANSI Standards Action. Recent electronic copies are available on the ANSI Web Site at;

http://www.ansi.org/news_publications/periodicals/standards_action/standards_action.aspx?menuid=7.
Refer to ANSI Standards Action for the complete list of changes and new publications, standards developing organizations, and information about submitting comments. Electronic delivery of selected documents is available through ANSI at: http://webstore.ansi.org/ansidocstore/default.asp.

ANSI also lists standards actions on new and revised American National Standards and International Standards Organization (ISO) Standards.

2.2 American Society of Mechanical Engineers (ASME)

ASME lists recently published standards on the ASME web site at: http://catalog.asme.org/home.cfm?Category=CS. Refer to the ASME web site for the complete list of changes and new publications, standards developing organizations, and information about submitting comments.

ASME maintains monthly updates of drafted new standards as well as revised drafts of current standards, to meet new requirements at: http://cstools.asme.org/csconnect/PublicReviewpage.cfm.

A respective "Comment Period End Date" follows each listed document.

2.3 ASTM International

The listing of approved ASTM standards actions during February 2006 is accessible at http://www.astm.org/cgi-bin/SoftCart.exe/SNEWS/FEBRUARY_2006/index.html?E+mystore. Refer to the ASTM web site for the complete list of new publications.

2.4 American Nuclear Society (ANS)

The ANS "What's New" web page at http://www.ans.org/standards/new/ lists recently initiated projects, as well as ANS standards approved in recent years.

2.5 National Fire Protection Association (NFPA)

The February 2006 NFPA News lists NFPA standards available for comment, newly proposed standards, newly issued standards, and the call for members on committees. View it at: http://www.nfpa.org/assets/files//nfpanews0206.pdf.

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THE STANDARDS FORUM & STANDARDS ACTIONS

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Standards Actions and *The Standards Forum and Standards Actions* are electronic newsletters available on the TSP web site (**http://tis.eh.doe.gov/techstds/**). To update your mailing list and/or e-mail addresses, please email us at **TechStdPgm@eh.doe.gov** or call Norm Schwartz at 301-903-2996.

Questions or Comments: If you have any questions or comments, please contact Jeff Feit, EH-22, Manager, DOE Technical Standards Program Office (TSPO), Phone: 301-903-0471, Fax: 301-903-6172, e-mail: Jeffrey.feit@eh.doe.gov